IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of:

Inventors:	Busch, et al.
Serial No:	10/652,861
Filed:	August 29, 2003
Title:	A BIATRIAL TRIPLE-CHAMBER CARDIAC PACEMAKER WITH MULTI-CONDITIONAL INHIBITION OF SECOND ATRIAL STIMULATION
Assignee:	Biotronik GmbH & Co. KG Woermannkehre 1 Berlin, GERMANY D-12359
Art Unit:	3762
Examiner:	Flory, Christopher A.

APPEAL BRIEF

To: Mail Stop Appeal Brief- Patents
The Honorable Commissioner of Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

In response to the Examiner's Final Office Action of May 7, 2007, and in view of the Notice of Appeal and Pre-Appeal Brief Request for Review filed by the Applicants on June 25, 2007, and in view of the Notice of Panel Decision from Pre-Appeal Brief Review of August 3, 2007 by which Applicants Appeal to the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office of the rejection, made 'Final' of the at least twice rejected claims 1-16 in the above-identified patent application.

The Applicant's Brief on Appeal is filed after at one month of the Pre-Brief Appeal Conference Decision on August 3, 2007 and, therefore, no extension of time is required.

The Applicants' Brief on Appeal is filed with the requisite filing fee under 37 C.F.R. § 41.20(b) (2) of $500.00. Please charge Deposit Account 15-0450 for any and all fees due for this paper.

This brief contains these items under the following headings and in the order set forth below (37 C.F.R. § 41.37):

I. Real Party in Interest
II. Related Appeals and Interferences
III. Status of Claims
IV. Status of Amendments
V. Summary of the Claimed Subject Matter
VI. Grounds of Rejection to be Reviewed on Appeal
VII. Arguments
VIII. Claims Appendix
IX. Evidence Appendix
X. Related Proceedings Appendix

The final page of this brief bears the practitioner's signature.

I. Real Party in Interest

The real party in interest in the present application is Biotronik GmbH & Co. KG Woermannkehre 1 Berlin, GERMANY D-12359, by assignment from inventors Ulrich Busch, and the legal representative of inventor Dr. Max Schaldach (deceased) who is Dr. Max Schaldach, Jr. on October 10, 2003 and October 2, 2003, respectively. The assignment is recorded in the United States Patent and Trademark Office at Reel 019291, Frame 0555.

II. Related Appeals and Interferences

There have been no interferences relating to this pending application, nor any related appeal or litigation.

III. Status of Claims

The status of the clams in this application is:

1. **Total Number of Claims in Application**

Claims 1-16 are pending in the application, being a total of 16 claims. No claims are allowed. Claims 1-16 are rejected and now under appeal.

2. **Status of All of the Claims**

A. Claims cancelled: None.
B. Claims withdrawn from consideration but not cancelled: None.
C. Claims pending: 1-16.
D. Claims allowed: None.
E. Claims objected to: None.
F. Claims rejected: 1-16.

3. **Claims on Appeal**

The claims on appeal are claims 1-16.

IV. Status of Amendments

The claims were last amended on September 5, 2006 at the time of filing of an Amendment in response to Examiner's Office Action of June 5, 2006 in this matter.

No amendments have been filed, subsequent to the rejection from which this appeal was originally taken, contained in the Office Action mailed May 5, 2007. A notice of appeal was filed June 25, 2007.

V. Summary of the Claimed Subject Matter

All citations to the specification refer to the substitute specification filed on April 9, 2004. As claimed in independent claim 1, the present invention relates to a biatrial triple-chamber pacemaker 10 for use with a heart 14 having a first and a second atrium and a first and a second ventricle (Paragraph [0017], lines 1-14). The pacemaker 10 comprises at least one sensing unit A_{RS} and A_{LS} (Fig. 1) for sense events A_R-Sense of the first atrium (Paragraph [0025], lines 2-3) and A_L-Sense of the first ventricle (Paragraph [0025], line 4). At least one

stimulation unit 30 (Fig. 1) is adapted to produce stimulation pulses to the second atrium and the first ventricle (paragraph [0025], lines 6-7, paragraph [0028], lines 1-3). A control unit 32 is connected to the sensing unit A_{LS} and/or A_{RS} (Fig. 1) and the stimulation unit 30 (Fig. 1) and is adapted to evaluate, for actuating the stimulation unit, at least the atrial sense events (A_R-Sense) associated with the first atrium (Paragraph [0025], lines 1-7) and the ventricular sense events (V-Sense) associated with the first ventricle (Paragraph [0026], lines 1-5). The stimulation unit is actuated with regard to a ventricular escape interval and a postatrial ventricular blanking time such that an occurrence of the atrial sense event (A_R-Sense) triggers the ventricular escape interval (Paragraph [0027, lines 1-3), at the end of which a ventricular stimulation pulse is triggered if same is not inhibited by an occurrence of the ventricular sense event within the ventricular escape interval and outside the postatrial ventricular blanking time (paragraph [0028], lines 1-8). The stimulation unit is actuated with regard to an interatrial conduction time such that an occurrence of the atrial sense event (A_R-Sense) triggers the interatrial conduction time (Paragraph [0025], lines 1-3), at the end of which a stimulation pulse to the second atrium is triggered if the stimulation pulse to the second atrium is not inhibited (Paragraph [0030], lines 7-16). The stimulation unit is actuated such that the delivery of a stimulation pulse to the second atrium is suppressed when previously an occurrence of the ventricular sense event occurs in a crosstalk window which adjoins a postatrial ventricular blanking time and at the same time a time interval, between a last ventricular sensed event occurring outside the crosstalk window and a next possible (scheduled) ventricular stimulation event, is greater than a predetermined maximum value (Paragraph [0030], lines 1-16).

As claimed in independent claim 2, a biatrial triple-chamber cardiac pacemaker 10 for use with a heart 14 having a first and a second atrium and a first and a second ventricle (Paragraph [0017], lines 1-14). The pacemaker 10 comprises at least one sensing unit A_{RS} and A_{LS} (Fig. 1) for sense events A_R-Sense of the first atrium (Paragraph [0025], lines 2-3) and A_L-Sense of the first ventricle (Paragraph [0025], line 4). At least one stimulation unit 30 (Fig. 1) is adapted to produce stimulation pulses to the second atrium and the first ventricle (Paragraph [0025], lines 6-7, paragraph [0028], lines 1-3). A control unit 32 is connected to the sensing unit A_{LS} and/or A_{RS} (Fig. 1) and the stimulation unit 30 (Fig. 1) and is adapted to evaluate, for actuating the stimulation unit, at least the atrial sense events (A_R-Sense) associated with the first

atrium (Paragraph [0025], lines 1-7) and the ventricular sense events (V-Sense) associated with the first ventricle (Paragraph [0026], lines 1-5). The stimulation unit is actuated with regard to a ventricular escape interval and a postatrial ventricular blanking time such that an occurrence of the atrial sense event (A_R-Sense) triggers the ventricular escape interval (Paragraph [0027, lines 1-3), at the end of which a ventricular stimulation pulse is triggered if same is not inhibited by an occurrence of the ventricular sense event within the ventricular escape interval and outside the postatrial ventricular blanking time (paragraph [0028], lines 1-8). The stimulation unit is actuated with regard to an interatrial conduction time such that an occurrence of the atrial sense event (A_R-Sense) triggers the interatrial conduction time (Paragraph [0025], lines 1-3), at the end of which a stimulation pulse to the second atrium is triggered if the stimulation pulse to the second atrium is not inhibited (Paragraph [0030], lines 7-16). The stimulation unit is actuated such that the delivery of a stimulation pulse to the second atrium is suppressed when a ventricular sense event occurs during an upper tracking interval operating mode in which the cardiac pacemaker works at a predetermined maximum stimulation rate (Paragraph [0031], lines 1-17).

VI. Grounds of Rejection to be Reviewed on Appeal

The current grounds of rejection are from the Office Action of May 7, 2007.

The Examiner rejected claims 1 and 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. In the rejection, the Examiner states that claims 1 and 2 require the stimulation unit to be "actuated with regard to an interatrial conduction time".

The Examiner rejected claims 1 and 2 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. In the rejection, the Examiner states that the omitted elements are: a sensing unit to sense events of the second atrium so as to facilitate measuring of an interatrial conduction time.

The Examiner rejected claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Limousin (U.S. Patent No. 5,514,161), hereinafter Limousin. In the rejection, the Examiner states that Limousin teaches of a double atrial triple chamber cardiac pacemaker, comprising at least one sensing unit for sensing events of a first atrium and a first ventricle (see for example col. 3 lines 50-53), at least one stimulation unit that is adapted to produce stimulation pulses to a second atrium (see for example col. 2 lines 37-43) and the first ventricle (see for example col. 2

lines 37-43), a control unit (col. 3 lines 17-27). The Examiner takes the position that it is inherent in the system as taught by Limousin to provide ventricular stimulation pulse in the absence of sensed vetricular event after an atrial sensed event triggers a ventricular escape interval (see for example col. 4 lines 38-49), since this is the reason for providing ventricular stimulation (see for example col. 4 lines 5-7), or in the alternative it is well known in the art to stimulate the ventricle in the absence of sensed ventricular event at the conclusion ventricular escape interval, and it would have been obvious to one having ordinary skill in the art to modify the system as taught by Limousin to provide ventricular stimulation under such conditions. The Examiner also takes the position that Limousin teaches of stimulating a second atrium in regards to interatrial conduction time (16) if the stimulation pulse is not inhibited (see for example col. 6 lines 4-13). The Examiner further takes the position that Limousin teaches that the delivery of a stimulation pulse to a second atrium is suppressed if a ventricular sensed event occurs in a crosstalk/listening window (see for example col. 5 lines 61-67 and col. 6 lines 1-4), and if the time between the previous ventricular event that occurred outside of the listening window and the time of the next possible ventricular event can be measured by the system and determined to be greater than what would be expected for an acceptable time period/interval (col. 6 lines 17-20), similarly to the process Limousin teaches of for measurements of sensed atrial signals (see for example col. 5 lines 40-60). Or, in the alternative, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Limousin to include a timing of an interval between such ventricular events and comparing it to a predetermine value/interval. Furthermore, with regard to claim 2, the Examiner states that Limousin teaches of suppressing the delivery of a stimulation pulse to the second atrium (see for example col. 5 lines 61-67 and col. 6 lines 1-4) and inherently has the ability to do so when the system is working the maximum stimulation rate, since there is no teaching that it is not capable of doing such.

VII. Argument

Grouping of Claims

The claims under appeal include independent claims 1 and 2, and dependent claims 3-16. The claims rise or fall together.

Legal Basis for Argument

The statutory standard under 35 U.S.C. §112, first paragraph, is that the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The Examiner is required to establish a *prima facie* case by providing reasons why a person of ordinary skill in the art would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. (MPEP §§ 2163, 2163.04)

It must be pointed out that there is no *in haec verba* requirement regarding compliance with the written description requirement. (MPEP §§ 2163 I.B., 2163.02) Possession of the claimed invention may be shown "by disclosure of drawings …that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole" (MPEP § 2163 II.A.3.(a)) or "by describing the claimed invention with all its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention." (MPEP §§ 2163.02) Also, a description that discloses "a device that inherently performs a function or has a property … necessarily discloses that function theory or advantage…" (MPEP §§ 2163.07(a))

The statutory standard under 35 U.S.C. §112, second paragraph, is that the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The statutory standard under 35 U.S.C. §102(b) is that a person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention. *Structural Rubber Products Co., v. Park Rubber Co., 749 F.2d 7070; 223 U.S.P.Q. 1264 (Fed. Cir. 1984).* Anticipation cannot be predicated on teachings in a reference that are vague or based on conjecture. *Datascope Corp. v. SMEC Inc.,*

594 F. Supp. 1036; 224 U.S.P.Q. 694, 698 (D.N.J. 1984). "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The test for anticipation requires that all of the claimed elements must be found in exactly the same situation and united in the same way to perform the same function in a single unit of the prior art. *Studiengesellschaft Kohle, m.b.H. v. Dart Industries., Inc., 762 F.2d 724, 726, 220 U.S.P.Q. 841 at 842 (Fed. Cir. 1984).*

The statutory standard under 35 U.S.C. §103(a) is that a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A claimed invention is unpatentable under 35 U.S.C. §103 if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C. § 103 (1994); *Graham v. John Deere Co.,* 383 U.S. 1, 14 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries, including (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18.

The Supreme Court has issued its opinion in KSR, regarding the issue of obviousness under 35 U.S.C. §103(a) when the claim recites a combination of elements of the prior art. *KSR Int'l Co. v. Teleflex, Inc.,* No 04-1350 (U.S. Apr. 30, 2007). The Court reaffirmed the *Graham* factors in the determination of obviousness under 35 U.S.C. §103(a). The four factual inquiries under *Graham* are:

(a) determining the scope and contents of the prior art;

(b) ascertaining the differences between the prior art and the claims in issue;

(c) resolving the level of ordinary skill in the pertinent art; and

(d) evaluating evidence of secondary consideration.

Graham v. John Deere, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

The Court did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. §103(a).

The Court rejected a rigid application of the "teaching, suggestion, or motivation" (TSM) test, which required a showing of some teaching, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the prior art elements in the manner claimed in the application or patent before holding the claimed subject matter to be obvious.

The Court noted that **the analysis supporting a rejection under 35 U.S.C. §103(a) should be made explicit, and that it was "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed**.

The Court specifically stated:

> Often, it will be necessary…to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.

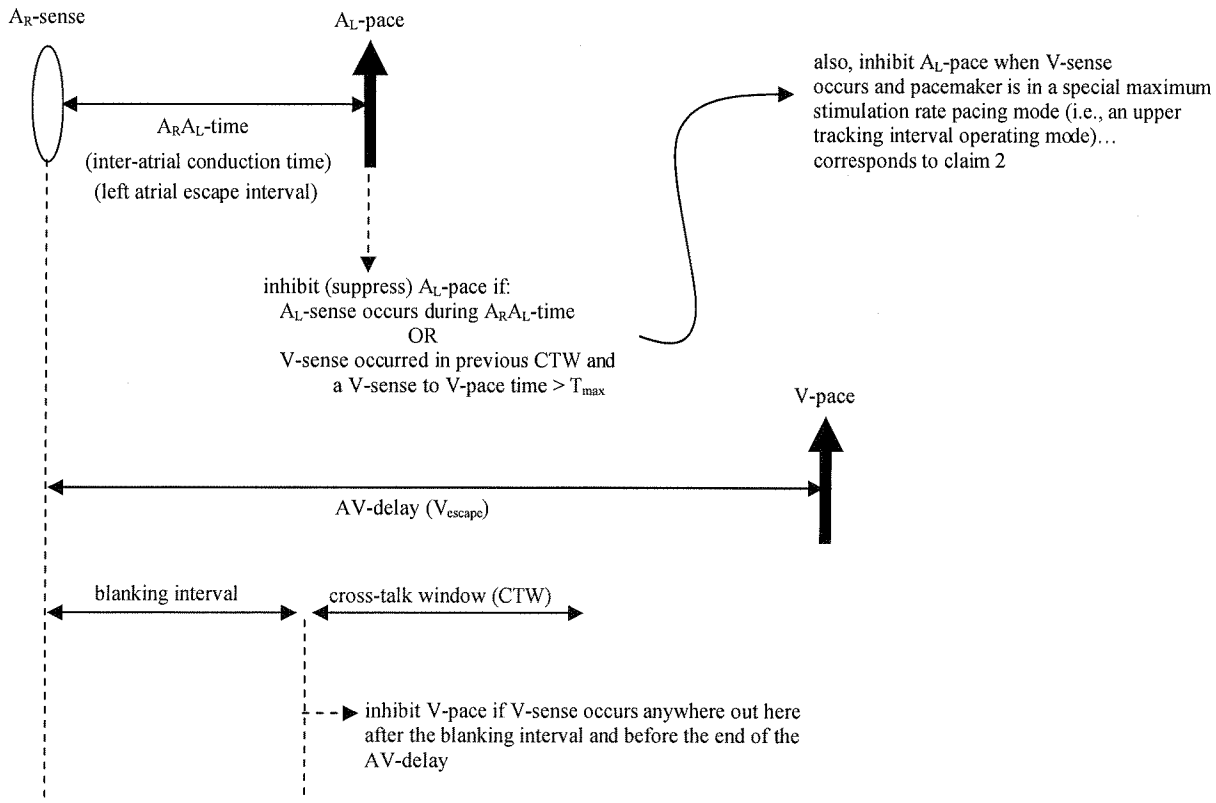
KSR, slip op. at 14 (emphasis added).

Therefore, in formulating a rejection under 35 U.S.C. §103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.

Rejection under 35 U.S.C. 103(a) as being unpatentable over Limousin (U.S. Patent No. 5,514,161).

Claims 1-16

The figure below characterizes the conditions under which the stimulation unit is actuated in accordance with independent claims 1 and 2 of the present application as described in the present application. Referring to the figure below, the occurrence of a right atrial sense event (A_R-sense) triggers an inter-atrial conduction time (also known as a A_RA_L-time or a left atrial escape interval) which is an artificial time controlled by a timer (not a natural A_RA_L-time). The occurrence of a right atrial sense event (A_R-sense) also triggers a ventricular escape interval V_{escape} (AV-delay) including a blanking interval followed by a cross-talk window (CTW) time.



At the end of the A_RA_L-time, a stimulation pulse A_L-pace to the second atrium (left atrium) is triggered unless inhibited. A_L-pace may be inhibited if a left atrial sense event (A_L-sense) occurs during the A_RA_L-time, or if a ventrical sense event (V-sense) occurred in the

previous CTW and, at the same time, a time interval (V-sense to V-pace) between a last ventricular sensed event occurring outside the CTW and a next possible (scheduled) ventricular stimulation event (V-pace) is greater than a predetermined maximum value (T_{max}). Also, if the pacemaker of the present invention is in a special maximum stimulation rate pacing mode (i.e., an upper tracking interval operating mode), then A_L-pace will be inhibited when a V-sense occurs. Furthermore, a ventricular stimulation pulse (V-pace) will occur at the end of V_{escape} unless there was the occurrence of a ventricular sense event (V-sense) within the V_{escape} interval but outside of the blanking interval. Such limitations of claims 1 and 2 of the present application are not taught or suggested by Limousin, and are certainly not obvious in light of the complexity to these actuating conditions of the stimulation unit.

In contrast to claims 1 and 2 of the present application, Limousin describes (see column 5 lines 39-67 to column 6 lines 1-16) an atrial circuit that senses and measures the interval between two successive sensed atrial signals. An evaluation is made of the diminution or rate of diminution of that time interval and is compared to a predetermined limit value. If the limit value is not exceeded, the situation is considered normal and an atrial stimulation is immediately provided to both atria. If the limit value is exceeded, a "window of listening" is opened on the ventricular electrode. If a signal is sensed on the ventricular electrode during the listening window, no atrial stimulation is provided. If no signal is sensed, the atrium is then stimulated at the end of the listening window. Such operation of Limousin is clearly quite different than that of claims 1 and 2 of the present application with respect to actuating a stimulation unit as described above. Any equivalence of Limousin to claims 1 and 2, with respect to the conditions under which a stimulation unit is actuated, as suggested by the Examiner in the Final Office action of May 7, 2007 are errors in fact. Furthermore, Limousin seems to require that both atria (right and left) be stimulated at the same time. Such simultaneous stimulation of atria would seem to prevent the proper operation of the pacemaker of claims 1 and 2 of the present application.

Therefore, the differences between the claimed invention and the prior art are NOT such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art, as required by the test for obviousness under 35 U.S.C. 103(a).

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claims 1 and 2 are not rendered obvious by Limousin, and it is respectfully submitted that claims 1 and 2 define allowable subject matter. Also, since claims 3-16 depend either directly or indirectly from independent claims 1 or 2, and since Applicants respectfully submit that independent claims 1 and 2 are not obvious over Limousin, as argued above herein, it is respectfully submitted that claims 3-16 are allowable as well.

Rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claims 1 and 2

The interatrial conduction time (A_RA_L-time) is an artificially controlled time which is intiated by A_R-sense as described above and as described in the present application and, therefore, has nothing to do with more than one sensing unit being present. The one sensing unit (e.g., the A_R sensing unit) and one stimulation unit (e.g., the A_L stimulation unit) are all that are relevant with respect to the A_RA_L-time for claims 1 and claims 2 of the present invention. Furthermore, it should be noted that, by means of a switch, a single atrial sensing unit and a single atrial stimulation unit could theoretically be used for independently sensing atrial events in the right and the left atrium and for generating right and left atrial stimulation pulses by means of the switch.

Therefore, the claimed invention does comply with the enablement requirement under 35 U.S.C. 112, first paragraph.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 and independent claim 2 comply with 35 U.S.C., first paragraph, and it is respectfully submitted that claim 1 and claim 2 define allowable subject matter.

Rejection under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements.

Claims 1 and 2

The interatrial conduction time (A_RA_L-time) is an artificially controlled time which is intiated by A_R-sense as described above and as described in the present application and, therefore, has nothing to do with more than one sensing unit being present as suggested by the Examiner. The one sensing unit (e.g., the A_R sensing unit) and one stimulation unit (e.g., the A_L stimulation unit) are all that are relevant with respect to the A_RA_L-time for claims 1 and claims 2 of the present invention. Furthermore, it should be noted that, by means of a switch, a single atrial sensing unit and a single atrial stimulation unit could theoretically be used for independently sensing atrial events in the right and the left atrium and for generating right and left atrial stimulation pulses by means of the switch.

Therefore, the claimed invention does not omit essential elements as required by 35 U.S.C. 112, second paragraph.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 and independent claim 2 comply with 35 U.S.C., second paragraph, and it is respectfully submitted that claim 1 and claim 2 define allowable subject matter.

Conclusion

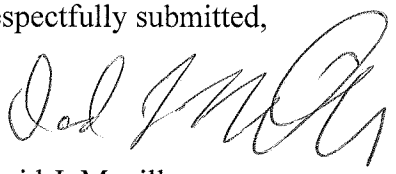
Applicants respectfully submit that none of claims 1-16 are rendered obvious by Limousin. The Examiner's reasons for such rejections, as outlined in the section herein "Grounds of Rejection to be Reviewed on Appeal", have been refuted herein.

Furthermore, Applicants respectfully submit the specification of the present application meets the enablement requirement with respect to at least claims 1 and 2 and does not omit essential elements, amounting to a gap between the elements.

With respect to independent claims 1 and 2, the operational configuration of Limousin is clearly quite different than that of claims 1 and 2 of the present application with respect to actuating a stimulation unit as described herein. The limitations of claims 1 and 2 of the present application are not taught or suggested by Limousin, and are certainly not obvious in light of the complexity of the actuating conditions of the stimulation unit. Therefore, the differences between the claimed invention and the prior art are not such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the are, as required by the test for obviousness under 35 U.S.C. 103(a).

Withdrawal of the rejection of the claims under 35 U.S.C. § 112, first paragraph, 35 U.S.C. § 112, second paragraph, and 35 U.S.C. 103(a), and the issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,



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VIII. Claims Appendix

1. A biatrial triple-chamber pacemaker for use with a heart having a first and a second atrium and a first and a second ventricle, said pacemaker comprising:

at least one sensing unit for sense events of the first atrium and the first ventricle;

at least one stimulation unit which is adapted to produce stimulation pulses to the second atrium and the first ventricle; and

a control unit which is connected to the sensing unit and the stimulation unit and which is adapted to evaluate, for actuating the stimulation unit, at least the atrial sense events (A_R-Sense) associated with the first atrium and the ventricular sense events (V-Sense) associated with the first ventricle;

wherein the stimulation unit is actuated with regard to a ventricular escape interval and a postatrial ventricular blanking time such that an occurrence of the atrial sense event (A_R-Sense) triggers the ventricular escape interval, at the end of which a ventricular stimulation pulse is triggered if same is not inhibited by an occurrence of the ventricular sense event within the ventricular escape interval and outside the postatrial ventricular blanking time,

wherein the stimulation unit is actuated with regard to an interatrial conduction time such that an occurrence of the atrial sense event (A_R-Sense) triggers the interatrial conduction time, at the end of which a stimulation pulse to the second atrium is triggered if the stimulation pulse to the second atrium is not inhibited, and

wherein the stimulation unit is actuated such that the delivery of a stimulation pulse to the second atrium is suppressed when previously an occurrence of the ventricular sense event occurs in a crosstalk window which adjoins a postatrial ventricular blanking time and at the same time a time interval, between a last ventricular sensed event occurring outside the crosstalk window and a next possible (scheduled) ventricular stimulation event, is greater than a predetermined maximum value.

2. A biatrial triple-chamber cardiac pacemaker for use with a heart having a first and a second atrium and a first and a second ventricle, said pacemaker comprising:

at least one sensing unit for sense events of the first atrium and the first ventricle;

at least one stimulation unit which is adapted to produce stimulation pulses to the second atrium and the first ventricle; and

a control unit which is connected to the sensing unit and the stimulation unit and which is adapted to evaluate, for actuating the stimulation unit, at least the atrial sense events (A_R-Sense) associated with the first atrium and the ventricular sense events (V-Sense) associated with the first ventricle;

wherein the stimulation unit is actuated with regard to a ventricular escape interval and a postatrial ventricular blanking time such that an occurrence of the atrial sense event (A_R-Sense) triggers the ventricular escape interval, at the end of which a ventricular stimulation pulse is triggered if same is not inhibited by an occurrence of the ~~a~~ ventricular sense event within the ventricular escape interval and outside the postatrial ventricular blanking time;

wherein the stimulation unit is actuated with regard to an interatrial conduction time such that an occurrence of the atrial sense event (A_R-Sense) triggers the interatrial conduction time, at the end of which a stimulation pulse to the second atrium is triggered if the stimulation pulse to the second atrium is not inhibited; and

wherein the stimulation unit is actuated such that the delivery of a stimulation pulse to the second atrium is suppressed when a ventricular sense event occurs during an upper tracking interval operating mode in which the cardiac pacemaker works at a predetermined maximum stimulation rate.

3. The pacemaker of claim 2, further comprising:

a further sensing unit for sense events of the second atrium, wherein the delivery of a stimulation pulse to the second atrium is suppressed when the further sensing unit produces a signal which is characteristic of a sense event (A_L-Sense) of the second atrium within the interatrial conduction time.

4. The pacemaker of claim 3, wherein:

the control unit is adapted to calculate the time spacing from a latest secured ventricular event to a next planned ventricular stimulation pulse.

5. The pacemaker of claim 4, wherein:

the control unit is adapted to compare the calculated time spacing to a predeterminable maximum value.

6. The pacemaker of claim 5, wherein:

the control unit is adapted to switch off interatrial synchronisation in dependence on the comparison between the calculated time spacing and the predetermined maximum value.

7. The pacemaker of claim 1, further comprising:

a further sensing unit for sense events of the second atrium, wherein the delivery of a stimulation pulse to the second atrium is suppressed when the further sensing unit produces a signal which is characteristic of a sense event (A_L-Sense) of the second atrium within the interatrial conduction time.

8. The pacemaker of claim 1, wherein:

the control unit is adapted to calculate the time spacing from a latest secured ventricular event to a next planned ventricular stimulation pulse.

9. The pacemaker of claim 7, wherein:

the control unit is adapted to calculate the time spacing from a latest secured ventricular event to a next planned ventricular stimulation pulse.

10. The pacemaker of claim 2, wherein:

the control unit is adapted to calculate the time spacing from a latest secured ventricular event to a next planned ventricular stimulation pulse.

11. The pacemaker of claim 8, wherein:

the control unit is adapted to compare the calculated time spacing to a predeterminable maximum value.

12. The pacemaker of claim 9, wherein:

the control unit is adapted to compare the calculated time spacing to a predeterminable maximum value.

13. The pacemaker of claim 10, wherein:

the control unit is adapted to compare the calculated time spacing to a predeterminable maximum value.

14. The pacemaker of claim 11, wherein:

the control unit is adapted to switch off interatrial synchronisation in dependence on the comparison between the calculated time spacing and the predetermined maximum value.

15. The pacemaker of claim 12, wherein:

the control unit is adapted to switch off interatrial synchronisation in dependence on the comparison between the calculated time spacing and the predetermined maximum value.

16. The pacemaker of claim 13, wherein:

the control unit is adapted to switch off interatrial synchronisation in dependence on the comparison between the calculated time spacing and the predetermined maximum value.

IX. Evidence Appendix

Exhibit A – Office Action dated May 7, 2007.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,861	08/29/2003	Ulrich Busch	117163.00087	1001

21324 7590 05/07/2007

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EXAMINER	
FLORY, CHRISTOPHER A	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
05/07/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
akron-docket@hotmail.com

Office Action Summary	Application No.	Applicant(s)	
	10/652,861	BUSCH ET AL.	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The new title of invention filed 5 September 2006 is sufficiently descriptive to overcome the objection of the previous Office Action filed 5 June 2006.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1 and 2 both require the stimulation unit to be "actuated with regard to an interatrial conduction time." Applicant has asserted in the reply filed 5 September 2006 on page 12, paragraph 3, that the Limousin reference only discloses one single atrial circuit, and therefore there cannot be anything like an interatrial interval between activation of the right and left atria. It is noted in response that claims 1 and 2 of the instant application, as written, also only disclose sensing unit(s) for a single (first) atrium, and therefore also lack the ability to determine an interatrial conduction time as later required in the claim. The disclosure of "at least one sensing unit" is stated in relation to a first atrium, so that even the inclusion of multiple sensing units can only be

read as to provide additional sensing abilities within the first atrium and not a second atrium. Therefore, the instant application lacks the ability to sense or actuate with regard to an interatrial conduction time.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a sensing unit to sense events of the second atrium so as to facilitate measuring of an interatrial conduction time.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The following rejections are based on prior art, which can be applied to the claims as to the best of the understanding of the Examiner.

Claims 1-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Limousin (U.S. Patent No. 5,514,161).

In regards to claims 1 and 2, Examiner is interpreting both a "sensing unit" and "stimulation unit" to be electrodes, or in the alternative the circuitry required to perform sensing and stimulation. Limousin teaches of a double atrial triple chamber cardiac pacemaker, comprising at least one sensing unit for sensing events of a first atrium and a first ventricle (see for example col. 3 lines 50-53), at least one stimulation unit that is adapted to produce stimulation pulses to a second atrium (see for example col. 2 lines 37-43 and the first ventricle (see for example col. 2 lines 37-43), a control unit (col. 3 lines 17-27). Examiner takes the position that it is inherent in the system as taught by Limousin to provide ventricular stimulation pulse in the absence of sensed ventricular event after an atrial sensed event triggers a ventricular escape interval (see for example col. 4 lines 38-49), since this is the reason for providing ventricular stimulation (see for example col. 4 lines 5-7), or in the alternative it is well known in the art to stimulate the ventricle in the absence of sensed ventricular event at the conclusion ventricular escape interval, and it would have been obvious to one having ordinary skill in the art to modify the system as taught by Limousin to provide ventricular stimulation under such conditions. Examiner also takes the position that Limousin teaches of stimulating a second atrium in regards to interatrial conduction time (16) if the stimulation pulse is not inhibited (see for example col. 6 lines 4-13).

Further in regards to claims 1 and 2, Examiner takes the position that Limousin teaches that the delivery of a stimulation pulse to a second atrium is suppressed if a ventricular sensed event occurs in a crosstalk/listening window (see for example col. 5 lines 61-67 and col. 6 lines 1-4), and if the time between the previous ventricular event

that occurred outside of the listening window and the time of the next possible ventricular event can be measured by the system and determined to be greater than what would be expected for an acceptable time period/interval (col. 6 lines 17-20), similarly to the process Limousin teaches of for measurements of sensed atrial signals (see for example col. 5 lines 40-60). Or in the alternative, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Limousin to include a timing of an interval between such ventricular events and comparing it to a predetermine value/interval.

Further regarding claim 2, Limousin teaches of suppressing the delivery of a stimulation pulse to the second atrium (see for example col. 5 lines 61-67 and col. 6 lines 1-4) and inherently has the ability to do so when the system is working the maximum stimulation rate, since there no is teaching that it is not capable of doing such.

In regards to claims 3 and 7, again Examiner interprets "sensing unit" to be an electrode or the circuitry required for sensing. Limousin teaches of sensing in the right atrium (col. 3 lines 53-63), which Examiner interprets broadly to include a separate sensing unit. Or in the alternative, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a separate (multiple sensing units), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St Regis Paper Co. v. Bemis Co., 193 USPQ 8. Further, in regards to claims 3 and 7, Examiner takes the position that the Limousin system is capable of suppressing the stimulation of the second atrium in light of a signal which is characteristic of a left atrial sensed event (see for example col. 3 lines 53-63),

or in the alternative, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Limousin to suppress the stimulation of the second atrium in light of left atrial sensed event (see for example col. col. 3 lines 63-67 and col. 4 lines 1-5.

In regards to claims 4-6 and 8-16, Examiner take the position that Limousin system teaches of calculating the time spacing between a ventricular event and a planned ventricular stimulation, and further comparing the calculated timed spacing to a predetermined value (see for example col. 6 lines 17-20 and col. 5 lines 40-60). Or in the alternative, the calculating of a interval between ventricular events and further comparing the events to a predetermined time is well know in the art and would have been an obvious modification to the Limousin system to one having ordinary skill in the art at the time of the invention.

Response to Arguments

8. Applicant's arguments, see page 8 paragraph 5 through page 9 paragraph 3, filed 5 September 2006, with respect to the 35 U.S.C. §112, 1st paragraph rejection of claims 3 and 7 have been fully considered and are persuasive. The §112, 1st paragraph rejection of claims 3 and 7 has been withdrawn.

9. Applicant's arguments, see page 9, paragraph 4 through page 10, paragraph 3, filed 5 September 2006, with respect to the 35 U.S.C. §112, 2nd paragraph rejection of claim 1 have been fully considered and are persuasive. The §112, second paragraph rejection of claim 1 has been withdrawn in light of the fact that Applicant has clarified

that two conditions must be fulfilled simultaneously in order to inhibit second atrium stimulation.

10. Applicant's arguments filed 5 September 2006 have been fully considered but they are not persuasive. Claims 1-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Limousin (U.S. Patent No. 5,514,161).

Applicant argues that Limousin only discloses one single atrial circuit and therefore cannot provide anything like an interatrial interval, stated as an essential feature of claims 1 and 2. As is noted above in the §112 rejection, the instant application also discloses only a single atrial sensing circuit and is therefore held to also fail to disclose the ability to provide an interatrial interval. Furthermore, Limousin clearly discloses in the abstract and in column 5, lines 39-65--cited by the Applicant—that the Limousin device is capable of calculating an A-A interval, and further that the PP interval is read as an interatrial interval as well.

Applicant also argues that the crosstalk window of the instant application is not identical or equivalent to the listening window of Limousin. However, the Examiner maintains that the crosstalk and listening windows are equivalents, since both relate to a post-atrial ventricular sense on the ventricular channel of the system. As such, the Examiner fails to see any structural or functional variance between the two circuits, and considers them to be equivalents in the art.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

16 April 2007

George Manuel
Primary Examiner

Exhibit B – U.S. Patent No. 5,514,161 to Limousin, first considered by the Examiner on May 26, 2006 from the Information Disclosure Statement submitted on April 9, 2004.

US005514161A

United States Patent [19]

Limousin

[11] Patent Number: 5,514,161

[45] Date of Patent: May 7, 1996

[54] **METHODS AND APPARATUS FOR CONTROLLING ATRIAL STIMULATION IN A DOUBLE ATRIAL TRIPLE CHAMBER CARDIAC PACEMAKER**

[75] Inventor: **Marcel Limousin**, Montrouge, France

[73] Assignee: **ELA Medical S.A.**, Montrouge, France

[21] Appl. No.: **416,308**

[22] Filed: **Apr. 4, 1995**

[30] **Foreign Application Priority Data**

Apr. 5, 1994 [FR] France 94 03988

[51] **Int. Cl.**[6] **A61N 1/368**

[52] **U.S. Cl.** **607/9**; 607/14

[58] **Field of Search** 607/9, 14, 19

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,932,406	6/1990	Berkovits .	
5,107,850	4/1992	Olive .	
5,226,415	7/1993	Girodo et al. .	

FOREIGN PATENT DOCUMENTS

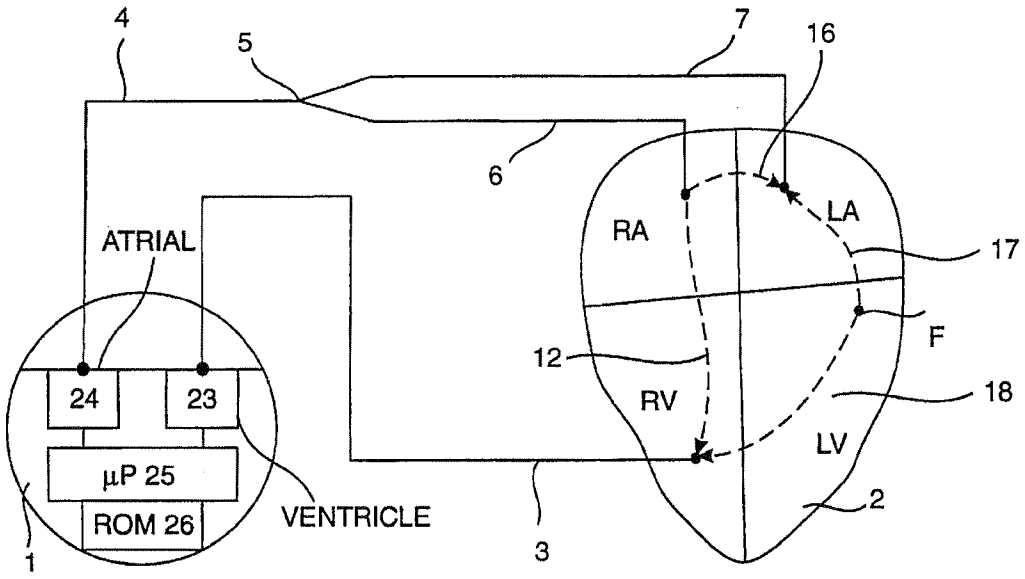
2544989	4/1983	France	A61N 1/36
WO9209331	6/1992	WIPO	A61N 1/368
WO9214511	9/1992	WIPO	A61N 1/368

Primary Examiner—William E. Kamm
Assistant Examiner—Scott M. Getzow
Attorney, Agent, or Firm—Orrick Herrington & Sutcliffe

[57] **ABSTRACT**

Process for controlling a double atrial triple chamber pacemaker having a right atrial electrode and a left atrial electrode connected to one and the same atrial circuit for the detection/stimulation of the atrium, as well as a ventricular electrode connected to a ventricular circuit for the detection/stimulation of the ventricle. The control process includes receiving at the input of the atrial circuit and the ventricular circuit a succession of depolarization signals, determining a possibly premature character of the depolarization signal sensed at the input of the atrial circuit, in case of determined prematurity, examining, during the duration of a predetermined window of listening, signals sensed at the input of the ventricular circuit and, in case of a ventricular signal reception, inhibiting all correlated atrial stimulation, and in the absence of sensing a ventricular signal, proceeding to an atrial stimulation at both atria at the end of the listening window duration, and, in the case of no prematurity character being found, proceeding to an immediate atrial stimulation in both atria synchronous to the detection of the sensed atrial depolarization signal.

6 Claims, 1 Drawing Sheet



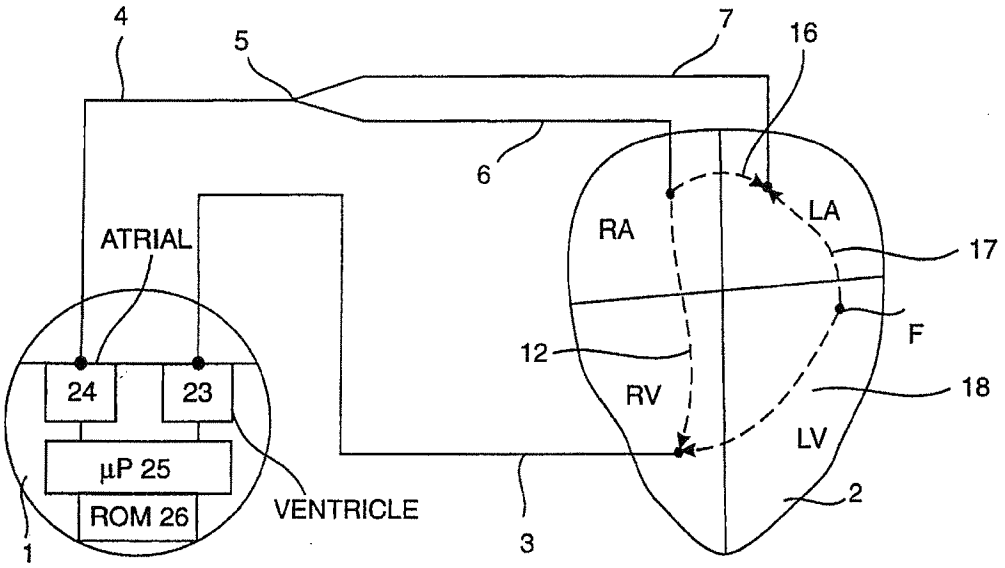

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FIG. 1

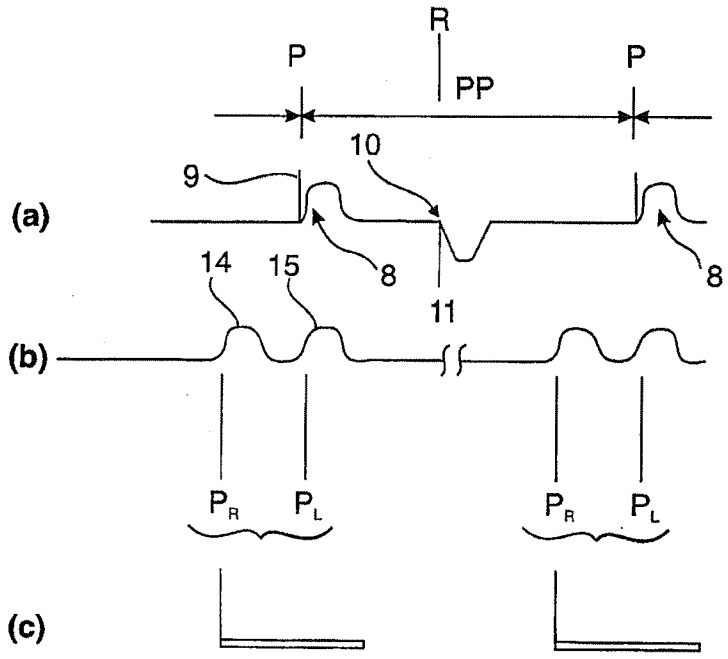
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FIG. 2

METHODS AND APPARATUS FOR CONTROLLING ATRIAL STIMULATION IN A DOUBLE ATRIAL TRIPLE CHAMBER CARDIAC PACEMAKER

FIELD OF THE INVENTION

The present invention concerns a cardiac pacemaker of the "double atrial triple chamber" type, in which there is possible sensing and stimulation of the right ventricle and each of the two atria, right and left.

BACKGROUND OF THE INVENTION

Triple chamber pacemakers typically include a ventricular electrode (generally a bipolar endocardial lead), and two atrial electrodes which are respectively implanted on each of the two atria and commonly connected to a corresponding single input port of the pacemaker. The common connection is typically a Y connector.

In a classic "bipolar electrode" the two conductive extremities, namely the distal and proximal terminals, are separated by only a few millimeters. In the atrial bipolar electrode for use in a double atrial triple chamber pacemaker in accordance with the present invention, however, the distal and proximal terminals are relatively spaced apart much further, e.g., a typical distance on the order of 5 cm, so that one electrode terminal is implanted in the right atrium and the other electrode terminal is implanted in the left atrium.

Triple chamber cardiac pacemakers have been used in a relatively satisfactory manner for some years. They are useful in connection with patients having indications presenting an "intra-atrial block" sinusal disorder, in which there is a deficient propagation of conduction (either insufficient or too long) from the right atrium to the left atrium.

Thus, if only one of the atria is stimulated (e.g., the right atrium, as in the classic situation of a "double chamber" pacemaker), the other atrium (e.g., the left atrium), which is not stimulated, would receive the depolarization wave coming from the stimulated atrium, if at all, after an excessively long period. In some cases, the period is longer than the atrial-ventricular delay (AV delay). Such a phenomenon can result in a contraction of ventricles occurring before the left atrium has finished draining, and, therefore, before the mistral valve has closed. This produces a counter-flow of blood from the ventricle to the left atrium and a diminution of the hemodynamic efficiency.

In addition, the electrical desynchronisation of the two atria favors the occurrence of tachyarrhythmia events.

Further, it has been recognized that the inter-atrial propagation delay period increases with the patient's effort. Therefore, the increase of the physiological activity of the patient apparently favors the risk of appearance of a such a syndrome.

The known triple chamber pacemakers operate by stimulating the left and right atria in a simultaneous manner. This is done to avoid the appearance or the persistence of the aforementioned phenomenon. Nevertheless, clinical studies have revealed the appearance of atrial tachyarrhythmia (AT) for some patients, notwithstanding such a systematic, simultaneous stimulation of the two atria. These AT, whose origin had not up until now been able to be identified, typically necessitated further treatment of patients by medication (for example, by administering a beta-blocking therapy). However, such medicinal treatments have a certain residual failure rate, such that a medicinal treatment is not always sufficient to prevent the appearance of recurrent AT in some patients. In addition, the treatment of the recurrent AT by medication is contraindicated absolutely in some patients.

OBJECTS AND SUMMARY OF THE INVENTION

It is, therefore, an object of the invention is to provide an improved control process for a double atrial triple chamber cardiac pacemaker which overcomes almost totally the recurrent AT having an unknown origin, which is associated with this type of device. It is another object to do so while avoiding the additional use of all medicinal treatments, and therefore the difficulties linked to contraindications and to secondary effects of the anti-arrhythmic agents that were heretofore believed necessary to use in supplement to the triple chamber pacemaker in certain patients.

The invention is essentially based on the inventors' discovery of a probable cause of the recurrent AT associated with the triple chamber pacemakers. More particularly, the inventors have recognized that, as will be explained in more detail below, recurrent AT are probably a "PMT" (Pacemaker-Mediated Tachyrhythmia) generated by an intervening confusion of the significance of the signals sensed at the level of atrial circuit. The confusion is caused by the appearance at the atrial circuit of sensed atrial signals in the form of a wave doublet indicative of an inter-atrium propagation time interval that is significant, and of the ventricular depolarization waveform from an ectopic event, notably if the ectopic event is situated near the left atrium. This confusion of sensed signals can result in starting an AV delay period which leads to a ventricular stimulation that is in turn susceptible to induce a recurring AT, i.e., a PMT.

An object of the invention is, therefore, to discriminate the sensed signals, namely to avoid the confusion at the atrial circuit between sensed signals that are ventricular in origin and atrial in origin, and thus to avoid the releasing of a reentrant tachycardia (PMT) which might lead to a persistent AT from a previously unknown origin associated with the triple chamber stimulation.

Broadly, the invention concerns the improved control of a cardiac pacemaker of the double atrial triple chamber type, comprising a right atrial electrode and a left atrial electrode that are connected to the same atrial circuit for the detection and stimulation for the atria of the pacemaker, as well as a ventricular electrode connected to a ventricular circuit for the detection and stimulation of the ventricle.

One aspect of the invention concerns a control process characterized by the steps of:

- receiving i.e., sensing, at the inputs of the atrial circuit and the ventricular circuit a succession of depolarization signals;
- determining whether or not the signal received at the input of the atrial circuit has a prematurity character;
- in case of a determined prematurity, examining, during a listening window of a predetermined duration, signals received at the input of the ventricular detection circuit,
  - in the case of a ventricular signal reception during the listening window, inhibiting all correlated atrial stimulation; and
  - in case of the absence of a ventricular signal reception during the listening window, stimulating the atria (both) at the end of the duration of the listening window; and
- in the case of no determined prematurity, proceeding to an immediate atria stimulation synchronous to the detection of the atrial depolarization signal sensed.

In one embodiment, the process step of determining whether or not the sensed signal has a prematurity character includes measuring the interval of time separating two

successive atrial signals, determining one of (i) the diminution, or (ii) the rate of diminution of this measured interval of time, and comparing the determined diminution or rate of diminution to a predetermined limit value, such that the prematurity condition is determined to exist when the limit value is exceeded.

In a second embodiment, the process step of determining the prematurity includes measuring the interval of time separating two successive signals, which may be either two successive atrial or two successive ventricular signals, counting, beginning with the last sensed ventricular event, a period corresponding to a predetermined fraction of the measured time interval, and analyzing signals received at the input of the atrial circuit during said period, wherein the prematurity condition is determined to exist when a signal is sensed at the atrial circuit during the period.

Another aspect of the invention concerns apparatus for controlling the pacemaker which includes logic circuits configured and operable to perform the aforementioned stimulation control process. Such apparatus logic circuits may be a microprocessor executing a software program stored in a memory device and signal conditioning (and digital conversion) circuits for sensing depolarization signals and processing the sensed signals in the manner described, or discrete logic circuits including latches, counters, flip-flops, comparators and gates configured for performing the same functions, albeit in a different way.

BRIEF DESCRIPTION OF THE DRAWINGS

Other characteristics and advantages of the invention will appear to a person of ordinary skill in the art in view of the following description of a preferred embodiment of the invention, made with reference to drawings annexed, in which:

FIG. **1** is a schematic view of the connection of a double atrial triple chamber pacemaker and the implantation of the atrial and ventricular endocardial electrodes on the myocardia (muscle) of the different cardiac chambers; and

FIGS. **2**(*a*) and **2**(*b*) illustrate the succession over time of the various depolarization waves received by the atrial circuit of the pacemaker of FIG. **1**, and FIG. **2**(*c*) illustrates a masking refractory period, illustrating the signal discriminative principles of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

With reference to FIG. **1**, the reference **1** designates a cardiac pacemaker, that is a typical DDD or DDT type device. Pacemaker **1** is a double bipolar pacemaker, in which there is both atrial and ventricular signal detection and ventricular and atrial stimulation, functioning in triggered mode. A triggered mode refers to producing a stimulation from the sensing of a signal on the corresponding electrode or, in an imposed manner, in the absence of a sensed signal after a given predetermined time.

The pacemaker **1** is connected to the myocardia **2** by a configuration of the triple chamber type, that is to say with a ventricular electrode **3** connected to the right ventricle RV and a double atrial electrode **4** connected to each of the two atria, the right atrium RA and the left atrium LA, by the intermediary of a Y connector **5**, and two respective electrode conductors (terminals) **6** and **7**. As a result of Y connector **5**, an atrial circuit **24** of detection/stimulation of the pacemaker **1** is connected to the electrode **4** at the common input, in a bipolar configuration for the detection and for delivering the stimulation pulse, and detects all signal received or sensed at each of electrodes **6** and **7** indifferently and, conversely, stimulates simultaneously and in an identical manner the two atria RA and LA. Such an atrial circuit **24** is well known in the art and may be of any type. The ventricular electrode **3** is connected to a ventricular circuit **23** for the sensing and stimulation of the ventricle, in a conventional manner well known in the art. Electrode **3** is preferably a conventional bipolar endocardial lead.

Such atrial circuits **24** and ventricular circuits **23** are known which can be separately and independently configured to sense cardiac activity in a bipolar mode or in a monopolar (unipolar) mode, the latter referencing one of the two bipolar terminals to the pacemaker case (relative ground). Suitable triple chamber cardiac pacemakers can be obtained by a modification of double chamber pacemakers such as those sold under the model name CHORUS II and CHORUS RM, available from ELA Medical of Montrouge France, and such that a double atrial electrode comprises two unipolar electrodes for implantation of one distal terminal in the left atrium and the other distal terminal in the right atrium and the Y connector. These CHORUS model pacemakers, similar to other double chamber pacemakers, include a microprocessor (**25**, FIG. **1**) and ROM **26** containing software instructions suitable for executing a DDT mode (and perhaps other modes) of pacing and the signal discrimination as described herein. The construction and programming of a software routine, and fixing of the program in a ROM **26** (or other memory device), to implement the triple chamber operation of the present invention are believed to be within the ordinary skill of the art.

The signal sensed by atrial circuit **24** follows generally the illustrated waveform shown in FIG. **2**(*a*), and comprises a succession of sensed atrial events **8** (P waves), such that the sensing of a P wave **8**, releases immediately an atrial stimulation, corresponding to the pulse peak **9** (FIG. **2**(*a*)). Consequently, both atria are simultaneously stimulated.

The atrial circuit **24** then senses the following ventricular depolarization wave **10** (an R wave) associated with the ventricle stimulation pulse peak **11** delivered to the right ventricle RV by the ventricular electrode **3**. The temporal gap between the P wave and the following R wave corresponds to the atrium-ventricle conduction delay (schematized by the dashed arrow **12** on the FIG. **1**). Of course, in case of a atrio-ventricular block or an anomaly of the same type, the ventricular circuit **23** of the pacemaker releases automatically the stimulation pulse if no ventricular R wave **10** is detected prior to the end of a predetermined AV delay interval.

In the particular case of the triple chamber stimulation, an atrial depolarization wave **8** can appear, in the absence of stimulation, in the manner illustrated in the larger scale of FIG. **2**(*b*), namely in the form of a wave doublet **14**, **15**. In the wave doublet, wave **14** corresponds to the P wave P_R of the right atrium RA and wave **15** corresponds to the P wave P_L of the left atrium LA. The spacing between the two waves **14** and **15** depends on the inter-atrial delay (schematized as dashed arrow **16** in FIG. **1**). The inter-atrial delay is variable according to each individual and, for each person, increases with the effort (activity level) of the patient.

As the inventors have realized, a ventricular wave depolarization, which has its origin at the level of the extremity terminal of electrode **3**, can appear as an ectopic focus of excitation. In such case, the wave origin is not found at the location of the electrodes, i.e., approximately at the extremity of electrodes **3**, **6**. Rather, in some cases, it can be found at a point F in the left ventricle LV that is relatively close to

the left atrium LA, for example, as illustrated in FIG. 1. Considering this relative proximity, the period of propagation from the focus F to the extremity terminal of the left atrial electrode 7, schematized as dashed arrow 17 in the FIG. 1, can be a short time duration. Indeed, the duration can be even shorter than the inter-atrial period schematized by dashed arrow 16.

Therefore, as the inventors have discovered, a depolarization waveform corresponding to an ectopic origin risks interfering with a depolarization wave front having an atrial origin, and being wrongly interpreted by the pacemaker as a subsequent atrial signal. As a result of the wrong interpretation, the pacemaker will release inopportunely an atrial stimulation. This is because the atrial stimulation is made synchronous with the atrial detection when the device is operating in a DDT mode. Such a premature atrial stimulation, which actually stimulates both of the atria, induces a tachycardia due to the existence of atrium-ventricle transmission 12 and, therefore, an anticipated contraction of the ventricle.

The result of this mechanism is a tachyarrhythmia that is identical in character to a tachycardia induced by the pacemaker (PMT). Hence, the inventors have discovered that this phenomenon of an electronically induced reentrant tachycardia (i.e., a PMT) which occurs in a significant number of patients with the use of the triple chamber pacemaker, is very probably the origin of the recurrent AT which have heretofore been known to exist with this type of device. Because the recurrent AT origin has been unexplained, it has been uncontrollable by operation of the device.

In order to minimize the recurrent AT phenomenon, the present invention proposes to operate a discrimination of signals sensed by the atrial circuit, and to operate the atrial stimulation only in response to a determined acceptable condition. This enhanced operation also functions to eliminate a response to the sensing of a sensed signal having an ectopic ventricular focus of excitation as an unacceptable condition.

To operate the discrimination control, in accordance with a first embodiment of the invention, the atrial circuit senses and measures in a continuous manner (e.g., by a microprocessor of the pacemaker or by discrete sensing circuits with a counter) the interval between two successive sensed atrial signals, represented by interval PP in FIG. 2(*a*). This value is updated in response to each new signal sensed at the input of the atrial circuit.

Next, an evaluation is made, at each new acquired measure, of either the diminution or the rate of diminution of this interval of time, that is to say the difference (absolute or relative, respectively) with the preceding measured value. Then, the determined diminution or the rate of diminution is compared to a predetermined limit value, for example, a maximal diminution of 125 ms, or a maximal diminution rate of 25%. Other specific limit values can be used, for example, a diminution of between 50 and 350 ms, and a rate of diminution of between 12.5 and 37.5%.

If this limit value is not exceeded, it is considered that the situation is normal, i.e., an acceptable condition, and an atrial stimulation is immediately provided to both atria.

If the limit value is exceeded, one opens a "window of listening" on the ventricular electrode, for example, a duration of 31 or 50 ms. The listening window is used to detect the possible appearance of a signal at the input of the ventricular circuit 23. If a signal is sensed in the limit of this listening window, this means that the signal last sensed on the atrial electrode likely originated from an ectopic ventricular depolarization, corresponding to the propagation path schematized by dashed arrow 18 in FIG. 1. In this case, no atrial stimulation is provided, so as to avoid inducing the appearance of a PMT as explained earlier. If, however, no signal is received during the duration of this listening window, it is considered that the signal last sensed on the atrial electrode was effectively a signal originating from the atrium, and that the observed atrial event acceleration was in fact a physiological acceleration of the atrium. Accordingly, this is an acceptable condition and the atrium is then stimulated at the end of the listening window. The stimulation is delivered at the end of the listening window so as to preserve a minimal delay. In addition, the AV delay interval released on this last atrial detection will typically be lengthened to maintain at least a duration corresponding to the preceding cardiac cycle.

Another manner of the determination of the premature or non premature character of the P wave, according to a second embodiment of the invention, is to trigger on ventricular events. To this end, after each ventricular event (a detection or a stimulation) one releases a period of suspicion of a ventricular extrasystole corresponding to a fraction of the interval between two preceding P waves (a P—P interval), or between two preceding R waves (an R—R interval). The fraction may be defined as a relative value (e.g., x% of the preceding interval) or in an absolute value (e.g., the preceding interval less x milliseconds), for example, a diminution of between 50 and 350 ms, and a rate of diminution of between 12.5 and 37.5%. If one detects during this suspicion period a signal at the input of the atrial circuit 24, then there is a suspicion of the presence of a ventricular extrasystole, and, as described in the aforementioned implementation, a listening window is opened on the ventricular electrode. The control process then continues to examine signals using the listening window in the same manner and with the same possible results as previously described in connection with the first embodiment.

Advantageously, the improved control process based on the aforementioned signal discrimination techniques reduces the recurrent AT and counter-flow phenomenon, and avoids the need for medicinal supplement, thereby obtaining improved double atrial triple chamber pacing.

One skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which are presented for purposes of illustration and not of limitation.

I claim:

1. A process for controlling a double atrial triple chamber cardiac pacemaker having an atrial circuit for detection and stimulation of the atrium, a ventricular circuit for detection and stimulation of the ventricle, a right atrial electrode, a left atrial electrode, the right and left atrial electrodes being connected to the atrial circuit, and a ventricular electrode connected to the ventricular circuit, comprising the steps of:

a) sensing at an input of the atrial circuit and the ventricular circuit a succession of depolarization signals;

b) sensing a depolarization signal at the input of the atrial circuit and determining whether or not the sensed depolarization signal has a prematurity character;

c) in case of a determined prematurity, examining during a predetermined listening window any depolarization signals sensed at the input of the ventricular circuit following said sensed depolarization signal, and:

i) in response to a sensed depolarization signal at the ventricular circuit input, inhibiting all atrial stimulation related to the determined prematurity, and

ii) in the absence of a sensed depolarization signal at the ventricular circuit input, delivering an atrial stimulation at the end of the listening window; and

d) in the absence of a determined prematurity, delivering an atrial stimulation synchronous to the sensed depolarization signal at the atrial circuit input.

2. The process of claim **1**, in which step (b) comprises:

measuring the interval of time separating a first and a second successive sensed depolarization signals at the atrial circuit input;

determining one of the diminution and the rate of diminution of said measured interval of time based on a first measured interval and for a second measured interval following the first measured interval; and

comparing the determined diminution or rate of diminution to a predetermined limit value and determining that the first sensed depolarization signal has said prematurity character in response to the predetermined limit value being exceeded.

3. The process of claim **1**, in which step (b) comprises:

measuring an interval of time separating one of two successive depolarization signals sensed at the atrial circuit input and two successive depolarization signals sensed at the ventricular circuit input;

counting, beginning from the last sensed ventricular event, a period corresponding to a predetermined fraction of said measured interval of time;

analyzing during said period signals sensed at the input of the atrial circuit; and

determining that the sensed depolarization signal has said prematurity character in response to an atrial signal being sensed during said period.

4. An apparatus for controlling a double atrial triple chamber cardiac pacemaker comprising:

an atrial circuit having an input to detect atrial events and to deliver stimulation pulses;

a first atrial electrode electrically connected to the atrial circuit input having a distal end to be coupled to one of the left and right atrium;

a second atrial electrode electrically connected to the atrial circuit input having a distal end to be coupled to the other of the left and right atrium;

a ventricular circuit having an input to detect ventricular events and to deliver stimulation pulses;

a ventricular electrode electrically connected to the ventricular circuit input and having a terminal to be coupled to a ventricle;

means for sensing a succession of depolarization signals at the inputs of the atrial and ventricular circuits;

means for determining whether or not a depolarization signal sensed at the input of the atrial circuit has a prematurity character;

means for processing the signal sensed at the input to the ventricular circuit during a predetermined time window in response to a sensed depolarization signal determined to have a prematurity condition;

means for controlling the delivery of an atrial stimulation operable in response to said processing means, wherein the occurrence of a ventricular signal sensed at the ventricular circuit input during the predetermined time window is operable to inhibit delivery of an atrial stimulation, and the absence of a ventricular signal sensed at the ventricular circuit input during said predetermined time window is operable to deliver a stimulation pulse at the end of the predetermined time window; and

means for processing the depolarization signal sensed at the input to the ventricular circuit during a predetermined time window in response to said sensed depolarization signal at the atrial circuit input not having a prematurity condition to deliver an atrial stimulation synchronous to the sensed depolarization signal at the atrial circuit input.

5. The apparatus of claim **4**, wherein the determining means further comprises:

a circuit to measure a time interval separating two successive atrial events;

means for determining a parameter corresponding to one of a diminution and a rate of diminution as between a first measured time interval and a second measured time interval following a first measured interval, and comparing the determined parameter to a predetermined limit value, wherein the prematurity character is present in response to the limit value being exceeded.

6. The apparatus of claim **4** wherein the determining means further comprises:

a circuit to measure a first time interval separating one of two successive atrial signals and two successive ventricular circuits;

means for timing a second time interval, beginning with the last sensed ventricular signal, corresponding to a predetermined fraction of said first time interval; and

means for analyzing during said second time interval any signals sensed at the input of the atrial circuit, wherein the prematurity character is present in response to an atrial signal being sensed during said second time interval.

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X. Related Proceedings Appendix

There are no related proceedings at this time.